## Practitioner's Docket No. MPI00-022P1RDV1M

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Rachel E. Meyers and Laura A. Rudolph-Owen

**Divisional Application** of Application No.:

N/A

Group No.:

Not Yet Assigned

Filed:

February 24, 2004

Examiner:

Not Yet Assigned

For:

26934, A NOVEL CYTIDINE DEAMINASE-LIKE MOLECULE AND USES

**THEREOF** 

Mail Stop Patent Application **Commissioner for Patents** 

P.O. Box 1450

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#### INFORMATION DISCLOSURE STATEMENT

# List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

- Preliminary Statements; 1. [x]
- Forms PTO/SB/08A and 08B (substitute for Form PTO-1449); 2. **[X]**
- Identification of Prior Application in Which Listed Information Was Already Cited and for 3. (x) Which No Copies Are Submitted or Need Be Submitted (1-8, U-X, 14-22)

#### CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

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## Practitioner's Docket No. MPI00-022P1RDV1M

#### **Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

# Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application Serial No. 09/802,371, filed on March 9, 2001.

The cited references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application. However, the undersigned will provide additional copies upon request.

February 24, 2004

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Attorney/Agent for Applicant

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Cambridge, MA 02139

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PTO/SB/08B (10-96)
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Complete if Known Substitute for form 1449B/PTO INFORMATION DISCLOSURE **Application Number** N/A Filing Date February 24, 2004 STATEMENT BY APPLICANT First Named Inventor Rachel E. Meyers, et al. **Group Art Unit** N/A (use as many sheets as necessary) **Examiner Name** N/A Sheet **Attorney Docket Number** MPI00-022P1RDV1M

	7	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Cite No.1		Include the name of the author (in CAPTIAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	
	1	Chan, et al., (1996) "Apolipoprotein B mRNA Editing Protein: A Tool for Dissecting Lipoprotein Metabolism and a Potential Therapeutic Gene for Hypercholesterolemia," Gastroenterol. 34(3):31-31.	
	2	Chang, et al., (1998) "Evolutionary Analysis of RNA Editing Enzymes," Methods Companion Methods Enzymol. 15(1):41-50.	
	3	Eliopoulos et al., (1999) "Chemoprotection Against Cytosine Nucleoside Analogs Using the Human Cytidine Deaminase Gene," Prog. Exp. Tum. Res. 36:124-142.	
	4	Smith et al., (1996) "Base-Modification mRNA Editing Through Deamination – the Good, the Bad and the Unregulated," TIG 12(10):418-424.	
	5	Verweij, (1999) "Rational Design of New Tumoractivated™ Cytotoxic Agents," Oncology 57(1):9-15.	
	6	NCBI Accession No. AC002369.	
	7	NCBI Accession No. AL078593.	
	8	NCBI Accession No. G38167.	
	U	Amino Acid and Nucleic Acid Sequence Match Database Sheets, Document WO/9902546 (January 21, 1999)	
<del></del> -	U	Nucleic acid and Amino Acid Database Sheets, Accession Number A1435527, April 13, 1999	_

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFC	RMATIC	ON DIS	CLOSURE	Application Number	N/A	
				Filing Date First Named Inventor	February 24, 2004	
SIA	STATEMENT BY APPLICANT				Rachel E. Meyers, et al.	
				Group Art Unit	N/A	
	(use as ma	any sheets as i	necessary)	Examiner Name	N/A	
Sheet	2	of	4	Attorney Docket Number	MPI00-022P1RDV1M	

	1	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPTIAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	
	U	Kappel et al, Regulating Gene Expression in Transgenic Animals, Current Opinion in Biotechnology 3: 548-553, 1992.	
	U	Mullins and Mullins., Perspective Series: Molecular Medicine in Genetically Engineered Animals, J. Clin. Invest. 98(11): S37-S40, 1996.	
	U	Mullins et al., Fulminant Hypertension in Transgenic Rats Harbouring the Mouse Ren-2 Gene. Nature 344: 541-544, April 5, 1990	
-11-11	V	Houdebine, Production of Pharmaceutical Proteins from Transgenic Animals. Journal of Biotechnology 34:269-287, 1994.	
	V	Rieger et al., Glossary of Genetics and Cytogenetics: Classical and Molecular, Fourth Completely Revised Edition, Springer-Verlag, New York, pages 17 and 18, 1976.	
	V	Taurog et al., HL-B27 in Inbred and Non-Inbred Transgenic Mice. The Journal of Immunology 141(11): 4020-4023, December 1, 1988.	
	V	Mullins and Mullins, Transgenesis in Nonmurine Species, Hypertension 22: 630-633, 1993	
	w	Wall, R.J., Transgenic Livestock: Progress and Prospects for the Future. Theriogenology 45: 57-68, 1996	
	w	Lazar et al., Transforming Growth Factor Alpha: Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities, Molecular and Cellular Biology 8(3): 1247-1252, March 1988.	

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INFO	RMATI	ON DIS	CLOSURE	Application Number	N/A		
CTA	STATEMENT BY APPLICANT			Filing Date	February 24, 2004		
SIA	ICIVICIA	IDIAL	PLICANI	First Named Inventor	Rachel E. Meyers, et al.		
				Group Art Unit	N/A		
	(use as many sheets as necessary)			Examiner Name	N/A		
Sheet	3	of	4	Attorney Docket Number	MPI00-022P1RDV1M		

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xaminer nitials*	Cite No.1	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	
***	w	Mullins, et al., Expression of the DBA/2J Ren-2 Gene in the Adrenal Gland of Transgenic Mice. The EMBO Journal 8(13): 4065-4072, 1989.	
	w	Niemann, H., Transgenic Farm Animals get off the Ground. Transgenic Research 7: 73-75, 1998.	
	x	Overbeek, Paul A., Transgenic Phemomenology Within Transgenic Animal Technology, A Laboratory Handbook Edited by Carl A. Pinkert, 1994.	
	X	Hammer, et al., Spontaneous Inflammatory Disease in Transgenic Rats Expressing HLA-B27 and Human Beta(2)Microglobin: An Animal Model of HLA-B27-Associated Human Disorders. Cell 63:1099-1112, November 30, 1990.	
	x	Niemann, H., Transgeneic Farm Animals Get off the Ground. Transgenic Research 7: 73-75, 1998	
	X	Cameron, Ewan R., Recent Advances in Transgenic Technology. Molecular Biotechnology 7: 253-265, 1997	
•••	14	Somasekaram, A., et al., "Intracellular Localization of Human Cytidine Deaminase, Identification of a Functional Nuclear Localization Signal," The Journal of Biological Chemistry, 1999, pp. 28405-28412, Vol. 274(40).	
	15	Weiner, K., et al., "Primary Structure of Human Deoxycytidylate Deaminase and Overexpression of its Functional Protein in Escherichia coli," The Journal of Biological Chemistry, 1993, pp. 12983-12989, Vol. 268(17).	
***************************************	16	EMBL Database Report for Accession No. AL138875, February 5, 2000 (XP-002186947)	-

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INIEC	PMATIC	ON DISC	CLOSURE	Application Number	N/A	
				Filing Date	February 24, 2004	
STA	STATEMENT BY APPLICANT			First Named Inventor	Rachel E. Meyers, et al.	
				Group Art Unit	N/A	
	(use as ma	any sheets as n	ecessary)	Examiner Name	N/A	
Sheet	4	of	4	Attorney Docket Number	MPI00-022PIRDVIM	

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	17	EMBL Database Report for Accession No. Al435527, March 16, 1999 (XP-002186948)	
	18	EMBL Database Report for Accession No. Al767392, June 30, 1999 (XP-002186949)	
	19	EMBL Database Report for Accession No. AWO73866, October 18, 1999 (XP-002186950)	
	20	EMBL Database Report for Accession No. Al142574, September 28, 1998 (XP-002186951)	
	21	EMBL Database Report for Accession No. BF114724, October 26, 2000 (XP-002186952)	
	22	EMBL Database Report for Accession No. Q9WYN5, November 12, 1999 (XP-002186953)	
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INFORMATION DISCLOSURE	Application Number	Not yet Assigned		
STATEMENT BY APPLICANT	Filing Date First Named Inventor	February 24, 2004 Rachel E. Meyers, et al.		
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U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	U.S. Patent Docume Kind Cod Number (if known	e²	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document (MM-DD-YYYY)	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	9	US 5,622,851	_	Maley, F. et al.	04-22-1997		
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	10	wo	97/05254	A1	Centre de Recherchie de L-Hopital	02-13-1997		
<u> </u>	11	wo	98/45472	A1	Harosh, I.	10-15-1998		
	12	wo	99/02546	A1	Human Genome Sciences, Inc	01-21-1999		
	13	EP	1,033,401	A2	Genset	09-06-2000		
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Rachel E. Meyers and Laura A. Rudolph-Owen

Divisional Application

N/A

Group No.:

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26934, A NOVEL CYTIDINE DEAMINASE-LIKE MOLECULE AND USES

**THEREOF** 

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# Practitioner's Docket No. MPI00-022P1RDV1M

(1) a final action under Section 1.113,
(2) a notice of allowance under Section 1.311, or
(3) an action that otherwise closes prosecution in the application
whichever occurs first.
[ ] Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).
[] Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).
[] No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).
FEE PAYMENT
2. [ ] The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).
(x) Applicant believes no fee is due in connection with this submission.
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February 24, 2004 MILLENNIUM PHARMACEUTICALS, INC.
By M fromst Tracy M. Sigussat

Attorney/Agent for Applicant

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